



Confirmation No. 2382

PC25870A

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

APPLICANT : David James Dooley, et al.

EXAMINER : Deborah D. Carr

SERIAL NO. : 10/734,917

ART UNIT : 1621

FILED : December 12, 2003

PAPER NO :

FOR : Alpha2delta Ligands for Fibromyalgia and Other Disorders

**Statement as Provided by 37 CFR 1.97(b)**  
**Required Submission Under 37 CFR 1.114(C)**

Mail Stop: RCE  
Commissioner for Patents  
P.O. BOX 1450  
Alexandria, VA 22313-1450

Dear Sir:

With regard to the above-identified application, Applicants hereby submit an Information Disclosure Statement (IDS) on the enclosed Form PTO/SB/08A. The items of information listed on the enclosed form are brought to the attention of the Examiner. The IDS accompanies a Request for Continued Examination (RCE), and serves as the required submission under 37 C.F.R. § 1.114(c).

This statement should be considered because it is submitted before the mailing date of a first Office Action on-the-merits, following the filing of the RCE.

In accordance with 37 C.F.R. § 1.98(a)(2), a copy of each document or other information listed on the enclosed Form PTO/SB/08A is provided.

In addition, a copy of a previously filed Form PTO/SB/08A is attached for the Examiner's convenience. Applicants request that the Examiner consider the references on the previously submitted Form PTO/SB/08A along with those from the newly filed Form PTO/SB/08A.

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102 and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish that the reference(s) are not "prior art." Moreover, Applicants do not represent that a reference has been thoroughly reviewed or that any relevance of any portion of a reference is intended.

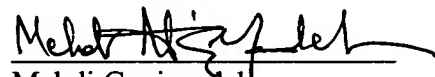
Consideration of the items listed is respectfully requested. Pursuant to the provisions of M.P.E.P. 609, it is requested that the Examiner return a copy of each of the attached PTO/SB/08A Forms initialed as being considered by the Examiner, to the undersigned with the next official communication.

US SN 10/734,917  
Docket No. PC25870A  
Express Mail No. E545392623US  
FILED December 12, 2003

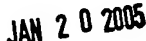
Authorization is hereby given to charge the required fee under 37 C.F.R. §1.17(p), any other necessary filing fees and any additional fees or credit any overpayment to Deposit Account 23-0455.

Respectfully submitted,

Dated: January 20, 2005

  
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Attachment: Previously filed Form PTO/SB/08A (3 Pgs)



Approved for use through 04/30/2003. OMB 0651-0031

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Substitute for form 1449/PTO

*(Use as many sheets as necessary)*

Sheet	1	of	2
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**Complete if Known**

Application Number	10/734,917
Filing Date	12/12/2003
First Named Inventor	David J. Dooley
Art Unit	1621
Examiner Name	Unknown
Attorney Docket Number	PC25870A

## U. S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	EP	0641330 B1	10-17-2001	R. B. Silverman, et al.		
	WO	98/17627 A1	04-30-1998	J. S. Bryans, et al.		
	WO	99/21824 A1	05-06-1999	J. S. Bryans, et al.		
	WO	00/76958 A2	12-21-2000	T. R. Belliotti, et al.		
	WO	01/28978 A1	04-26-2001	J. S. Bryans, et al.		
	WO	01/90052 A1	11-29-2001	J. S. Brvans, et al.		

Date  
Considered

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313

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The PTO did not receive the following listed item(s) all FOR'S

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PTO/SB/08B (08-00)  
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Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>				<b>Complete if Known</b>	
Sheet	2	of	2	Application Number	10/734,917
				Filing Date	December 12, 2003
				First Named Inventor	David J. Dooley
				Group Art Unit	1621
				Examiner Name	Unknown
				Attorney Docket Number	PC25870A

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		M. V. AMERINGEN et al., "Drugs in development for social anxiety disorder: more to social anxiety than meets the SSRI" Expert Opinion on Investigational Drugs, Ashley Pub. Ltd., London, GB 2000:2215-2231; Vol.9, No. 10	
		A. BARKHUIZEN, "Rational and targeted pharmacologic treatment of fibromyalgia" Rheum Dis Clin N Am 2002;28:261-290	
		R. M. BENNETT, "The rational management of fibromyalgia patients" Rheum Dis Clin N Am 2002; 28: 181-199	
		D. BUSKILA, "Fibromyalgia, chronic fatigue syndrome and myofascial pain syndrome" Current opinions in Rheumatology 2001;13:117-127	
		B. L. EHRENBERG, et al., "Open-Label Trial of Gabapentin for Periodic Limb Movement Disorder of Sleep", 1997, pp A278-A279, Vol. 48	
		E. K. GUYMER, et al., "An approach to managing fibromyalgia" Medicine Today 2002:58-59; Vol. 3, No. 12	
		L. J. LEVENTHAL, "Management of fibromyalgia" Ann Intern Med 1999;131:850-8	
		L. T. MELTZER, et al., "Pregabalin enhances non-rapid eye movement sleep and eeg slow-wave activity in rats" Society for neuro. abstracts 2001:2245 Vol. 27, No. 2	
		I. SELAK, "Pregabalin (Pfizer)" Current opinion in investigational drugs, current drugs, Lond, GB 2001:828-834; Vol. 2, No. 6	
		F. WOLFE, et al., "The American College of Rheumatology 1990 criteria for the classification of fibromyalgia: Report of the Multicenter Criteria Committee" Arthritis Rheum 1990; 33:160-72	
		M. B. YUNUS, "A comprehensive medical evaluation of patients with fibromyalgia syndrome" Rheum Dis N Am 2002; 28:201-217	

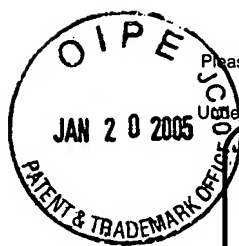
Examiner Signature		Date Considered	
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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449B/PTO  <h2 style="margin: 0;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="margin: 0;"><i>(use as many sheets as necessary)</i></p>				<b>Complete if Known</b>	
				Application Number	10/734,917
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				First Named Inventor	David J. Dooley
				Group Art Unit	1621
				Examiner Name	Unknown
				Attorney Docket Number	PC25870A

[illegible]

Examiner Signature		Date Considered	
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Confirmation No. 2382

PTO/SB/08A (08-03)

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/734,917
Filing Date	December 12, 2003
First Named Inventor	David James Dooley, et al.
Art Unit	1621
Examiner Name	Deborah D. Carr
Attorney Docket Number	PC25870A

Sheet 1 of 1

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 5,670,539	09-23-1997	Mary Ann Richardson	
		US- 5,919,823	07-06-1999	Mary Ann Richardson	
		US- 6,117,908	09-12-2000	Paul L. R. Andrews, et al.	
		US- 6,127,418	10-03-2000	Lionel Bueno, et al.	
		US- 6,248,363 B1	06-19-2001	Mahesh V. Patel, et al.	
		US- 6,309,663 B1	10-30-2001	Mahesh V. Patel, et al.	
		US- 6,310,098 B1	10-30-2001	Thomas J. Guttuso, Jr.	
		US- 6,372,792 B1	04-16-2002	Guy Chouinard	
		US- 2002-0035057 A1	03-21-2002	Virginia Pact Richter, et al.	
		US- 2002-0037926 A1	03-28-2002	Nancy C. Lan	
		US- 2002/0072538 A1	06-13-2002	Bertrand L. Chenard, et al.	
		US- 2002/0099013 A1	07-25-2002	Thomas Piccariello, et al.	
		US- 20020099092 A1	07-25-2002	David Clive Blakemore, et al.	
		US- 2002/0165246 A1	11-07-2002	Andrew Holman	
		US- 2003/0144214 A1	07-31-2003	David Clive Blakemore, et al.	
		US-			
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		US-			
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**FOREIGN PATENT DOCUMENTS**

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		Country Code <sup>3</sup> *Number <sup>4</sup> *Kind Code <sup>5</sup> (if known)				
		WO 01/13904 A2	03-01-2001	Ortho-Mcneil Pharmaceutical Inc.		
		WO 01/45714 A2	06-28-2001	Glaxo Group Limited		
		WO 02/34237 A1	05-02-2002	New River Pharmaceuticals Inc.		
		WO 03/061656 A1	07-31-2003	Endo Pharmaceuticals Inc.		
		DE 198 02 327 A1	07-29-1999	Godecke AG		

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